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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,569	07/11/2003	Robin A. Robinson	NOVV-003/00US	5752

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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07/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,569

Applicant(s)

ROBINSON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This action is in response to the paper filed 4/30/07.

Claims 34-55 are under consideration.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 34-42, and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* (J of Virology Vol 75, pages 6154-6165, from IDS) and Saito *et al.* (Vaccine 2001 Vol. 20 pages 125-133).

Applicant argues that the examiner has not met the burden of proof in establishing a *prima facie* case, citing that none of the cited references disclose HA or NA activity let alone an avian VLP with HA or NA activity, that obviousness cannot be predicated on what is not known at the time the invention was made, even if the inherency of a certain feature is later established, *In re Rijckaert*, 9 F.2d 1531,

28 USPQ2d 1955 (Fed. Cir. 1993). (MPEP 2141.02), that the VLPs of Latham *et al.* are not avian and do not teach HA and NA activity, and the examiner provides no evidence of activity, that even if the examiner provides a reference of HA and NA activity in vlps, it cannot be presumed that the VLPs of of Latham *et al.* have the activity, and thus and in conclusion, the examiner has not met his burden to of establishing a *prima facie* case.

Applicant's arguments have been fully considered and not found persuasive.

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Both Latham *et al.* and the specification make the VLPs by insect cells and would be expected to have the same properties as the instantly claimed VLPs.

- The VLPs of Latham *et al.* react with monoclonal antibodies in western blots and on fixed cells and are stated by Latham *et al.* to be useful as vaccines. The VLPs are shown to look like influenza virus particles (Figure 5). The proteins that make the VLP of Latham *et al.* appear to be wild type in structure and antibody binding. The VLPs of Latham *et al.* would be expected to have the HA and NA activity of influenza. The claims recite no structures that differentiate them from the VLPs of Latham *et al.* (2/16/06 Action)

The examiner has made a *prima facie* case.

The HA and NA activity are properties of the recited structure, not structural features that exist on their own. New properties of old compositions are not patentable.

The burden has shifted to applicant to show that the prior art VLPs do not have the recited functions (HA and NA activity). The fact that the primary prior art reference in the 103 rejection does not disclose avian VLPs is not an issue because the rejection is based on a combination of references. Applicant has not argued that there is no motivation to combine. Applicant provides no evidence that this is an unexpected result or that there is reason to doubt success.

Applicant's argument that obviousness cannot be predicated is not persuasive because *In re Rijckaert* deals with differences in structural features, not functions of the prior art structure.

The rejection is maintained for reasons set out above.

Claims 34, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* and Saito *et al.* as discussed above and Gupta *et al.* (Vaccine 2001 Vol. 14 pages 219-225).

Applicant argues that Latham *et al.* and Saito *et al.* have been discussed, that Gupta *et al.* do not teach influenza vaccines, and that the examiner has not met his burden to of establishing a *prima facie* case because the combined references do not teach all the limitations of the claims.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has not presented any arguments that there is no motivation to combine, any that the references do not teach all the limitations.

The response to arguments against Latham *et al.* and Saito *et al.* have been discussed above.

Gupta *et al.* teach in the art of adjuvants used in vaccines and teach an adjuvant that has desirable properties as discussed in the previous action (Discussion pages 223-224). Adjuvants are used to boost immune response to antigens.

Thus, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MGH
4/30/07


JEFFREY S. PARKIN, PH.D.
PRIMARY EXAMINER